Allergy Therapeutics

Interim results for the six months ending 31 December 2017

Delivering on our strategy – three areas for growth

March 2018
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Introduction to Allergy Therapeutics

Dedicated to allergy treatment and prevention

Leading allergy immunotherapy company with a portfolio of marketed products and strong development pipeline

Provide treatments that have potential to cure disease, not just symptoms. Focus on moderate to severe patients

Approximately 500 employees

Headquartered and manufacturing base in Worthing, West Sussex

Market capitalisation of approximately £150m, AIM ticker LSE:AGY

Double digit compound annual growth achieved over the past 18 years

Robust revenue growth and successful M&A delivered. Three pillar strategy for growth: Europe, pipeline and US

Spun out of Smith Kline Beecham in 1999

Products currently in trials for the US market
Financial highlights
~ Double digit compound annual growth achieved over the past 18 years ~

1.3%* increase in revenue at constant currency** to
£40.9m
(H1 2017: £40.4m)

4.4% increase in revenue at
£42.2m
(H1 2017 £40.4m)

Solid growth in operating profit pre R&D up

12% to £12.3m as a result of leveraging sales growth, a stated aim of management
(H1 2017: £11.1m)

R&D expenditure of
£5.9m
(H1 2017: £3.8m)

Cash balance of
£25.8m
(H1 2017: £27.8m)

*Percentage based on numbers in thousands (H1 2018: £40,956m, H1 2017: £40,427m)
** Constant currency uses prior year weighted average exchange rates to translate current year foreign currency denominated revenue to give a year on year comparison excluding the effects of foreign exchange movements. See table in financial review for an analysis of revenue.

N.B. All financial dates refer to the financial year. All clinical dates refer to the calendar year.
Operational highlights

- Solid revenue growth across Europe – strong performance from Venomil and Acarovac Plus
- Completion of recruitment for pivotal Phase III Pollinex Quattro Birch trial
- Completion of recruitment for US Grass Mata MPL Phase II trial ahead of schedule
- Contract for scale up of Polyvac peanut signed with aim for first trial in humans in 2019
- Acarovac Phase I trial continues with read out expected in H1 2019
- Contract for Oralvac joint development signed with Ergomed. TAV projects on track

Increased market share in Germany

14% (2017: 13%)
Delivering our strategy

Three pillars to the business

Expanding in Europe
- Strongly performing profitable business
- Growing market share and additional product registrations

Strong pipeline
- New technologies underpin pipeline breadth and depth
- Investment strategy supported by growing revenue stream

Preparing for US entry
- Significant opportunity in largest allergy market
- Changing environment to drive market share towards Allergy’s products
Delivering our strategy

EXPANDING IN EUROPE
Solid sales growth of 1.3%* in H1 2018 and increased German market share to 14% from 13% driven by:

- Innovative, convenient and patient-friendly (short-course) products
- Increased regulatory requirements to ATL advantage (TAV)
- Focused investment across business reflected in performance
- Strength of broad portfolio with Acarovac Plus and Venomil
- Scaling-up to drive technological and geographical expansion

Double digit CAGR growth over the last 18 years since formation (full year data)

*Percentage based on figures in thousands (H1 2018: £40.956m, H1 2017: £40.427m)
Sales breakdown for FY 2017

Sales by country

- **UK**: 4%
- **Netherlands**: 4%
- **Germany**: 59%
- **Czech Republic**: 2%
- **Slovakia**: 2%
- **Austria**: 7%
- **Switzerland**: 3%
- **Italy**: 9%
- **Spain**: 9%
- **Other**: 1%

Sales by product

1. **Sales breakdown based on gross sales at budget exchange rates (before freight, discounts, rebates and exchange): £63.2 million.**
2. **After deducting discounts, rebates, freight charges and foreign exchange adjustments, total sales for FY2017 is £64.1 million.**
Delivering our strategy

STRONG PIPELINE
TAV (Therapy Allergy Ordinance) process

Includes all products without registration

40% of all submitted products have now been removed from the process and are no longer on the market (PEI Seminar, 2017)

Germany contributes 59% of AGY Group sales

Future advantage of clinical evidence to support marketing plus potential reduction in competition

All of Allergy’s products submitted in 2011 are still in process

TAV German process initiated in 2008 and driven by the Paul Ehrlich Institute based on European legislation
# Broad pipeline

<table>
<thead>
<tr>
<th>also available as a named patient product</th>
<th>Market/Registered</th>
<th>Phase III</th>
<th>Phase II</th>
<th>Phase I</th>
<th>Pre-clinical</th>
</tr>
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<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Pollinex Grass</th>
<th>Short-course SCIT</th>
<th>Europe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pollinex Tree</td>
<td>Short-course SCIT</td>
<td>Europe</td>
</tr>
<tr>
<td>Pollinex Ragweed</td>
<td>Short-course SCIT</td>
<td>Canada</td>
</tr>
<tr>
<td>Venomil Bee</td>
<td>Bee venom SCIT</td>
<td>Europe</td>
</tr>
<tr>
<td>Venomil Wasp</td>
<td>Wasp venom SCIT</td>
<td>Europe</td>
</tr>
<tr>
<td>Pollinex Quattro Grass</td>
<td>Short-course Grass SCIT with MPL</td>
<td>Europe, USA</td>
</tr>
<tr>
<td>Pollinex Quattro Birch</td>
<td>Short-course Birch SCIT with MPL</td>
<td>Europe</td>
</tr>
<tr>
<td>Pollinex Quattro Ragweed</td>
<td>Short-course Ragweed SCIT with MPL</td>
<td>USA</td>
</tr>
<tr>
<td>Pollinex Quattro Grass</td>
<td>Short-course Grass SCIT with MPL</td>
<td>Europe, USA</td>
</tr>
<tr>
<td>Pollinex Quattro Trees</td>
<td>Short-course Tree SCIT with MPL</td>
<td>USA</td>
</tr>
<tr>
<td>Oralvac Grass, Trees &amp; house dust mite</td>
<td>Sublingual immunotherapy with flexible-dosing</td>
<td></td>
</tr>
<tr>
<td>Acarovac Platform</td>
<td>Short-course modified Allergen HDM SCIT + MPL</td>
<td></td>
</tr>
<tr>
<td>Polyvac Peanut</td>
<td>Short-course Peanut SCIT</td>
<td></td>
</tr>
</tbody>
</table>

* - 0.5mL formulation  
** - 1.0 mL formulation
Pipeline trials

Positive top-line results for Phase II Birch dosing study (B204) using conjunctival provocation test

**PQ Birch – Phase III (Germany – TAV process)**
- Recruitment completed and patients already being treated
- Results expected H2 2018
- If successful, regulatory submission 2019

**PQ Grass – Phase II (US & Germany TAV process)**
- Recruitment completed early and patients already being treated
- Results expected ahead of schedule in early H2 2018
- If successful, second Phase III study to follow in US/Europe

**Acarovac MPL Phase I**
- Trial with 32 patients in progress in Spain
- Results expected H1 2019
- Potential for US market with two Phase III trials
Polyvac peanut product

Positive results achieved from preclinical research of Polyvac Peanut

Single dose of virus like particle (VLP) combined with recombinant peanut allergen successfully protects against anaphylaxis when challenged with peanut

Those vaccinated with candidate vaccine exhibited no symptoms compared to placebo, when challenged with peanut

Safety profile of product evaluated and found not to induce anaphylaxis

Manufacturing contract for scale-up of Polyvac product signed with Biomeva with aim of having first in human trial in 2019

Peanut represents a new opportunity into $8bn* worldwide food allergy market

Pre-clinical development progressing according to plan with important product differentiation demonstrated – aim is long-term immunity

*The Journal of Allergy and Clinical Immunology 2016. 1% of US population. EACCI Food Allergy and Anaphylaxis Guidelines Group 2016 0.2% of Western European Population. Management assumption of annual treatment of $2k
Delivering our strategy

PREPARING FOR US ENTRY
Portfolio of products to capture US opportunity

- **Proprietary, IP protected technology**

- **De-risked opportunity**
  - Treated more than 250,000 patients and marketed in 7 countries (pollens)

- **First mover advantage**
  - First to market in the seasonal injected segment
  - High entry barriers: regulatory requirements for extensive trials on efficacy and safety

- **Strategic fit for US market**

- **Building on progress to date in the US:**
  - $100m invested in clinical studies to date
  - 15 clinical trials completed to date, including Phase I, II & III successful studies
  - Investigated in over 3,000 patients worldwide, mainly in the US
The evolving US opportunity

Estimated peak grass sales $300-400 million**

Currently no registered injected products

Some adherence levels as low as 15%*

Current treatment: up to 100 injections over 3-5 years***

2-3 million*** Americans receive allergy immunotherapy

$2 billion** estimated allergy immunotherapy market

**Internal estimate
***Professor Lawrence DuBuske MD
Financial results
### P&L – six months ended 31 December 2017

<table>
<thead>
<tr>
<th></th>
<th>H1 2018 £'m</th>
<th>H1 2017 £'m</th>
<th>Variance £'m</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>42.2</td>
<td>40.4</td>
<td>1.8</td>
<td>4%</td>
</tr>
<tr>
<td>Gross profit</td>
<td>33.5</td>
<td>31.5</td>
<td>2.0</td>
<td>6%</td>
</tr>
<tr>
<td>Overheads</td>
<td>(21.4)</td>
<td>(20.5)</td>
<td>(0.9)</td>
<td>(4%)</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>(5.9)</td>
<td>(3.8)</td>
<td>(2.1)</td>
<td></td>
</tr>
<tr>
<td>Other Income</td>
<td>0.2</td>
<td>0.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating profit</td>
<td>6.4</td>
<td>7.2</td>
<td>(0.8)</td>
<td></td>
</tr>
<tr>
<td>Net Financing costs</td>
<td>(0.0)</td>
<td>(0.0)</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Tax</td>
<td>(0.4)</td>
<td>(0.4)</td>
<td>(0.0)</td>
<td></td>
</tr>
<tr>
<td>Profit after tax</td>
<td>6.0</td>
<td>6.8</td>
<td>(0.8)</td>
<td></td>
</tr>
</tbody>
</table>

**Solid sales performance** in abnormally weak pollen season

**Sales drive gross profit growth**

**Overheads up** due to FX and investment

**Significant R&D investment last year** in US Grass study and PQ Birch in Europe

**Operating profit pre-R&D of £12.3m** (H1 2017: £11.1m) due to investment, leveraging solid sales
Sales – six months ended 31 December 2017

Strong sales increases in Spain and Eastern Europe

Most markets performing robustly

Strong growth in Venomil and Acarovac Plus

FX impact much lower in this period as smaller difference between rates

<table>
<thead>
<tr>
<th></th>
<th>H1 2018 £'m</th>
<th>H1 2017 £'m</th>
<th>Variance £'m</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross Revenue at Constant Exchange Rate</td>
<td>44.9</td>
<td>44.3</td>
<td>0.6</td>
<td>1%</td>
</tr>
<tr>
<td>Rebate at Constant Exchange Rate</td>
<td>(4.0)</td>
<td>(3.9)</td>
<td>(0.1)</td>
<td>(3%)</td>
</tr>
<tr>
<td>Net Revenue at Constant Exchange Rate</td>
<td>40.9</td>
<td>40.4</td>
<td>0.5</td>
<td>1%</td>
</tr>
</tbody>
</table>

**Effect of Foreign Exchange**

1.3

**Net Revenue**

42.2

40.4

1.8

4%

*Constant exchange rate Euro/£

1.16

Current exchange rate Euro/£

1.13

1.16
Balance sheet at 31 December 2017

<table>
<thead>
<tr>
<th></th>
<th>2018 (£'m)</th>
<th>2017 (£'m)</th>
<th>Var (£'m)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-current assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>9.8</td>
<td>9.7</td>
<td>0.1</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>5.1</td>
<td>5.4</td>
<td>(0.3)</td>
</tr>
<tr>
<td>Investments</td>
<td>4.9</td>
<td>4.3</td>
<td>0.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>19.8</strong></td>
<td><strong>19.4</strong></td>
<td><strong>0.4</strong></td>
</tr>
<tr>
<td><strong>Current Assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>10.9</td>
<td>10.7</td>
<td>0.2</td>
</tr>
<tr>
<td>Inventories</td>
<td>8.4</td>
<td>7.0</td>
<td>1.4</td>
</tr>
<tr>
<td>Cash</td>
<td>25.8</td>
<td>27.8</td>
<td>(2.0)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>35.9</strong></td>
<td><strong>38.5</strong></td>
<td><strong>(2.6)</strong></td>
</tr>
<tr>
<td><strong>Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financing liabilities</td>
<td>(3.2)</td>
<td>(3.4)</td>
<td>0.2</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>(25.8)</td>
<td>(23.0)</td>
<td>(2.8)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>(29.0)</td>
<td>(26.4)</td>
<td>(2.6)</td>
</tr>
<tr>
<td><strong>Net assets</strong></td>
<td><strong>35.9</strong></td>
<td><strong>38.5</strong></td>
<td><strong>(2.6)</strong></td>
</tr>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share capital and share premium</td>
<td>103.0</td>
<td>103.0</td>
<td>0.0</td>
</tr>
<tr>
<td>P&amp;L account and other reserves</td>
<td>(67.1)</td>
<td>(64.5)</td>
<td>(2.6)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>35.9</strong></td>
<td><strong>38.5</strong></td>
<td><strong>(2.6)</strong></td>
</tr>
</tbody>
</table>

**Increase in non-current assets**
Driven by increase in pension investments

**Inventory higher**
Due to preparation for clinical trial material

**Cash position**
Of £25.8m

**Debt of £3.2m**
Seasonal overdraft in place (undrawn)

**Other liabilities increase**
Due to R&D creditors
Cashflow for the six months ended 31 December 2017

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£'m</td>
<td>£'m</td>
</tr>
<tr>
<td>Opening cash balance 1st July</td>
<td>22.1</td>
<td>23.4</td>
</tr>
<tr>
<td>(Loss)/Profit before tax</td>
<td>6.4</td>
<td>7.2</td>
</tr>
<tr>
<td>Adjustments re operations</td>
<td>(2.1)</td>
<td>(1.7)</td>
</tr>
<tr>
<td>Net cash (used)/ generated by operations</td>
<td>4.3</td>
<td>5.5</td>
</tr>
<tr>
<td>Tax received/paid</td>
<td>0.7</td>
<td>0.0</td>
</tr>
<tr>
<td>Interest paid</td>
<td>(0.1)</td>
<td>(0.1)</td>
</tr>
<tr>
<td>Interest received</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Investments and acquisitions</td>
<td>(0.2)</td>
<td>(0.1)</td>
</tr>
<tr>
<td>Capital expenditure</td>
<td>(1.0)</td>
<td>(1.4)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(1.1)</td>
<td>(1.4)</td>
</tr>
<tr>
<td>Proceeds from issue of shares</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Net movement in borrowings</td>
<td>(0.1)</td>
<td>(0.1)</td>
</tr>
<tr>
<td>Net cash generated in financing activities</td>
<td>(0.1)</td>
<td>(0.1)</td>
</tr>
<tr>
<td>Effects of exchange rates on cash</td>
<td>0.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Closing Cash Balance 31 December</td>
<td>25.8</td>
<td>27.8</td>
</tr>
</tbody>
</table>

**Positive net cash generated** by growth in business and foreign exchange benefit

**Significant tax received** due to R&D tax credit from 2017 financial year

**Strong Cash position** of £25.8m driven by solid performance and timing of R&D investment
Summary and outlook
Summary and outlook
2018 set to be a pivotal year

Solid trading in H1 2018:

1.3*% sales growth at constant currency

14% market share Germany

Delivering against our strategy: three pillars to growth

Robust financials set to continue

Clinical trials progressing as planned – broad pipeline underpinned by innovative technologies

Focused strategy to be first to market in the US SCIT segment

2018 set to be a pivotal year:
- Growth and expansion in European business
- Results of pivotal Birch Phase III trial and US Grass Phase II trial
- Robust future product development pipeline

Board remains confident about Group’s future prospects

*Percentage based on figures in thousands (H1 2018: £40.956m, H1 2017: £40.427m)
2018 expected key value driving newsflow

- **Early H2 2018:**
  - PQ Grass Phase II for US and Europe – results of conjunctival provocation test dosing trial in Europe

- **H2 2018:**
  - PQ Birch Phase III for Europe
    - results of pivotal field trial for PQ technology and part of the TAV process

- **H1 2019:**
  - Acarovac MPL Phase I – results for the new dust mite technology which could be developed for the Global market

Full year results
Appendix
## Analysis of regulated products

<table>
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<tr>
<th>Vaccines</th>
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<tbody>
<tr>
<td><strong>Named patient basis</strong></td>
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<tr>
<td>Pollinex</td>
</tr>
<tr>
<td>Pollinex Quattro Grass</td>
</tr>
<tr>
<td>Pollinex Quattro Birch</td>
</tr>
<tr>
<td>Pollinex Quattro Ragweed</td>
</tr>
<tr>
<td>Pollinex Quattro Trees</td>
</tr>
<tr>
<td>Pollinex Quattro Grass &amp; Birch</td>
</tr>
<tr>
<td>Pollinex Quattro Grass &amp; Tree</td>
</tr>
<tr>
<td>Pollinex Quattro Grass &amp; Mugwort</td>
</tr>
<tr>
<td>Acarovac Plus</td>
</tr>
<tr>
<td>Acarovac MPL</td>
</tr>
<tr>
<td>TyroMILBE</td>
</tr>
<tr>
<td>Venomil</td>
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<td>TA Top</td>
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### Oral

<table>
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<tr>
<th>Oral</th>
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<tbody>
<tr>
<td><strong>Named patient basis</strong></td>
</tr>
<tr>
<td>Oralvac Grass</td>
</tr>
<tr>
<td>Oralvac Trees</td>
</tr>
<tr>
<td>Oralvac House Mite</td>
</tr>
</tbody>
</table>

¹ Approved in Germany or other major market

Trials in process: 
CMC process: 
Trials undertaken: 

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[Allergy Therapeutics](https://www.allergytherapeutics.com)
Global presence

Sales and marketing network comprising c.160 European sales force

Subsidiaries in 7 countries and distribution agreements in additional 14 countries
Changing US landscape to drive market share

Current US SCIT market

- Home made, unlicensed preparation
- Non GMP manufacturing
- Non registered
- No clinical evidence
- Long courses of treatment: 50 to 100 injections
- Slow to act: 6 to 12 months
- Low compliance

Allergy Therapeutics’ entry in the US

- Standardised dose vaccine
- GMP manufactured
- FDA submission
- Multiple clinical studies
- Ultra-short course treatment: 4 to 6 injections
- Efficacy in 3 weeks
- High compliance

New USP and FDA regulations drive towards pharmaceutical grade, centrally manufactured, single allergen treatments
Microcrystalline tyrosine (MCT)

Patent protection for MCT

Processing patent covers MCT

MCT particles are formulated as sterile in state of the art processes enabling defined particle morphology and size optimised for binding to wide variety of antigens.

MCT Process patent extended-UK (2032)/EU filing 2032

R&D update Allergy / Non – Allergy indications

Within the last 12 months, studies have been completed supporting MCT use as a depot immunomodulator in each application:

Key publication in The Journal of Inorganic Biochemistry provides insight to the role of the (MCT) for use in existing and future therapeutic development incl. synergies with MCT and MPL in our Pollinex Quattro brand

Immunomodulation of MCT in allergy (publication pending 2016) – University of Zurich

MCT improves efficacy in non-allergy models (Influenza, Malaria) – Public Health England, University of Oxford (Jenner Institute), respectively. (publication in preparation)

MCT to enhance immunogenicity of different vaccines – for malaria study
PQ: a unique platform technology

Pollinex Quattro:
4 injections in 3 weeks, efficacy in 3 weeks

**MPL Adjuvant**
- MPL (Monophosphoryl Lipid A) is a non-toxic derivative of lipopolysaccharide (LPS)
- MPL allows the SIT treatment course to be shortened (big impact on adherence)
- Regulates expression of co-stimulatory molecules on antigen-presenting cells
- Acts locally as a TLR4 agonist and increases IgG production

**Allergoid**
- Allergen chemically modified with glutaraldehyde
- Retains IgG-allergen stimulating properties
- Patient adherence
- Reduces IgE reactivity vs. that induced by native allergens used in SIT

**MCT**
- A natural amino acid which is readily metabolised
- L Tyrosine retains the Allergoid and MPL at the site of injection (half life = 48 hours) as depot
- 30-year history of safe use in vaccines
- Rebalances TH1 response
Acarovac MPL house dust mite product

**Phase I first patient treated**
- in June 2017 as part of 32 patient trial (AM101)

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**Acarovac product without MPL growing well in Spain and Austria**

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**Potential of 8 injection model**
- compared to 12-15 average of competitors and once a day for 3 years oral treatment

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**Results of Phase I Trial**
- expected H1 2019

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**Market opportunity of**
- $3-4bn* worldwide with only Europe partly tapped already

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**Potential additional product**
- in US portfolio following two Phase III trials

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*The Journal of Allergy and Clinical Immunology 2016. 1% of US population. EACCI Food Allergy and Anaphylaxis Guidelines Group 2016 0.2% of Western European Population. Management assumption of annual treatment of $2k
Bencard Adjuvant Systems division

**Strategy**

- MCT, MPL & VLP
  - Researching on MCT mechanism of action
  - Potential for licencing or use in development of products to boost efficiency

**Studies**

- Pre-clinical study using MCT in a seasonal influenza model – elicited immune response indicative of protection
  - Pre-clinical model using MCT and VLP in malaria – offered best protection compared with antigens formulated with aluminium
  - Studies show MCT both alone and in adjuvant system elicit high, sustained antibody titres demonstrating enhanced protective efficacy compared to conventional adjuvants including aluminium
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<th>Native Allergen</th>
<th>Recombinant Allergen</th>
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<th>Monophosphoryl Lipid A (MPL)</th>
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* - Product under pre-clinical investigation, full product profile yet to be determined
Notes:
1. While in the TAV process all products can continue to be sold. Once rejected they must be removed from the market.
2. All products must either have been approved or must go through the TAV process.
3. The trials needed are tolerability, dose ranging and efficacy.